

**Anexa 10 Lotul 10 Sterilizator 110L**

FN 500P, Nuve, Turcia

| Parametri solicitati                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Parametri oferiti                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Sterilizator 110 L<br>Cod 270330<br>Descriere Sterilizator cu aer uscat destinat sterilizării instrumentelor medicale cu consctruție interioară din oțel inox<br>Parametrul Specificația<br>Ventilație forțată, controlată electronic<br>Construcție interioară oțel inox<br>Construcție exterioară cu acoperire anticorozivă<br>Regimuri de sterilizare programabile<br>Protecție la supraîncălzire analogical digitală<br>Alarmer acustică vizuală<br>Diagnostic automat cu afișarea codului erorii<br>Volumul 110l, ±10 l<br>Camera sterilizatorului Să mențină steril instrumentele în interiorul camerei, să nu fie orificii cu acces direct la exterior<br>Temperatura 50 - 200°C<br>Divergență față de temperatura setată ≤ 1°C<br>Abatere timp ≤ 1 min<br>Timp încălzire până la temperatura setată ≤ 60 min<br>Regim de sterilizare prestabilite 180°C, 60 min<br>160°C, 150 min<br>120°C, 45 min<br>Rezoluția de programare 1°C<br>Timpul de răcire ≤ 35 min, pînă la 75°C<br>Deconectare de avariere la temperatura 205 - 235°C<br>Tipul de funcționare fără întrerupere ≥ 8 ore<br>Rafturi ≥ 3<br>Suport metal pentru instalarea sterilizatorului da<br>Alimentare 200-240V, 50 Hz | Sterilizator 110 L<br>Cod 270330<br>Descriere Sterilizator cu aer uscat destinat sterilizării instrumentelor medicale cu consctruție interioară din oțel inox<br>Parametrul Specificația<br>Ventilație forțată, controlată electronic<br>Construcție interioară oțel inox<br>Construcție exterioară cu acoperire anticorozivă<br>Regimuri de sterilizare programabile<br>Protecție la supraîncălzire analogical digitală<br>Alarmer acustică vizuală<br>Diagnostic automat cu afișarea codului erorii<br>Volumul 110 l<br>Camera sterilizatorului Să mențină steril instrumentele în interiorul camerei, să nu fie orificii cu acces direct la exterior<br>Temperatura +5 peste ambient - 250°C<br>Divergență față de temperatura setată 2°C<br>Abatere timp 1 min<br>Timp încălzire până la temperatura setată 60 min<br>Regim de sterilizare prestabilite – nu dispune. Se seteaza programa de catre utilizator<br><br>Rezoluția de programare 1°C<br>Timpul de răcire 35 min, pînă la 75°C<br>Deconectare de avariere la temperatura 205 - 235°C<br>Tipul de funcționare fără întrerupere 8 ore<br>Rafturi 3<br>Suport metal pentru instalarea sterilizatorului NU<br>Alimentare 200-240V, 50 Hz |

# EC DECLARATION OF CONFORMITY

We, NÜVE Sanayi Malzemeleri İmalat ve Ticaret A.Ş.  
Saracalar Mah. Saracalar Kümeevleri No: 4/2  
Akyurt 06750 Ankara / TURKEY

herewith declare that the following described product meets the provisions of the Council Directive 93/42/EEC (2007/47/EC) for Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

**PRODUCT:**

**DRY AIR STERILIZER**

**MODEL:**

**FN 300 / FN 400 / FN 500**

**CLASSIFICATION:**

**IIB, Annex IX - RULE 15**

**GMDN:**

**35364**

**CONFORMITY ASSESMENT ROUTE:**

**MDD 93/42/EEC (2007/47/EC), ANNEX II.3**

**APPLICABLE HARMONISED  
STANDARDS:**

|                |              |
|----------------|--------------|
| EN 60601-1     | EN 62366     |
| EN ISO 15223-1 | EN 60601-1-2 |
| EN 62304       | EN ISO 14971 |
| EN 60601-1-6   | EN 61000-6-3 |

**EUROPEAN REPRESENTATIVE:**

**Mr. Doram Elkayam  
OBELIS S.A.  
Av. de Tervuren 34, Bte 44,  
B-1040 Brussels - BELGIUM**

**NOTIFIED BODY:**

**KIWA MEYER  
BELGELENDİRME HİZMETLERİ A.Ş.  
(İTOSB) İstanbul Tuzla Organize Sanayi  
Bölgesi Tepeören Mevkii 34957 Tuzla-İstanbul  
TURKEY**

**CERTIFICATE NUMBER:**

**1984-MDD-10-030**

**DATE OF ISSUE:**

**May 29, 2015**

**SIGNATURE:**

  
**Beril IZGIN  
General Manager**

**CE**  
1984



# FN SERIES

## Dry Heat Sterilizers /Ovens

- Designed for the dry heat sterilization in medical, dentistry and veterinary applications
- Suitable for drying, warming and heating, heat treatment and long term stability tests in research and industrial laboratories
- Very homogeneous temperature distribution by natural air convection for FN 300/400/500 and by forced air ventilation for FN 400P/500P
- Anodic-oxidated aluminium chamber for FN 300/400/500 and stainless steel chamber for FN 400P/500P
- The door, pressing firmly and tightly on the chamber gasket to reduce temperature loss
- Adjustable outlet port for vapour exhaustion
- Reliable and accurate N-Prime™ programmable PID microprocessor control system
- User friendly control panel including large bright LED displays for temperature and time
- Easy programming with one button, just turn and push
- Password protected menu to secure the operation
- Programmable alarm limits
- Data recording on memory stick by means of USB port up to 125 days
- Programmable delayed start function
- Highly visible dual displays for temperature and time
- Adjustable independent safety thermostat which takes over control in case of any failure



**N-prime**

## TECHNICAL SPECIFICATIONS

|                                                | FN 300                                   | FN 400      | FN 400P         | FN 500                    | FN 500P         |
|------------------------------------------------|------------------------------------------|-------------|-----------------|---------------------------|-----------------|
| Temperature Range                              | Ambient Temp + 5°C / 250°C               |             |                 |                           |                 |
| Temperature Sensor                             | Fe-Const                                 |             |                 |                           |                 |
| Control System                                 | N-Prime™ Programmable Microprocessor     |             |                 |                           |                 |
| Temperature Set and Display Sensitivity        | 1°C                                      |             |                 |                           |                 |
| Temperature Variation (100°C-150°C)            | ± 2°C                                    |             |                 |                           |                 |
| Temperature Fluctuation                        | ± 1°C                                    |             |                 |                           |                 |
| Programmable Alarm Limits                      | ± 2°C / 10°C                             |             |                 |                           |                 |
| Timer                                          | 1 minute – 99,9 hours + Hold Position    |             |                 |                           |                 |
| Delayed Start Timer                            | 1 minute – 99,9 hours                    |             |                 |                           |                 |
| Selectable Recording Frequency on Memory Stick | 10 or 30 seconds, 1, 5, 30 or 60 minutes |             |                 |                           |                 |
| Useful Volume, litres                          | 22                                       | 48          | 42              | 120                       | 110             |
| Number of Shelves (Standard/ Max.)             | 2/6                                      | 2/7         | 2/7             | 2/10                      | 2/10            |
| Internal Material                              | Anodic-oxidated Aluminium                |             | Stainless Steel | Anodic-oxidated Aluminium | Stainless Steel |
| External Material                              | Epoxy - Polyester Powder Coated Steel    |             |                 |                           |                 |
| Power Consumption                              | 500 W                                    | 800 W       | 900 W           | 1600 W                    | 1550 W          |
| Power Supply                                   | 230 V, 50/60 Hz                          |             |                 |                           |                 |
| Internal Dimensions (WxDxH) mm.                | 300x240x300                              | 420x320x360 | 420x280x360     | 500x480x500               | 500x445x500     |
| External Dimensions (WxDxH) mm.                | 555x380x460                              | 705x475x540 | 705x505x540     | 785x630x680               | 785x665x680     |
| Packing Dimensions (WxDxH) mm.                 | 640x470x640                              | 790x570x750 | 790x580x760     | 870x740x860               | 870x740x860     |
| Net / Packed Weight kg.                        | 26 / 31                                  | 37 / 43     | 39 / 45         | 55 / 65                   | 66 / 74         |

## ACCESSORIES

|          |                             |
|----------|-----------------------------|
| R 01 014 | Aluminium Shelf for FN 300  |
| R 01 136 | Mesh type shelf for FN 400  |
| R 01 126 | Mesh type shelf for FN 400P |
| R 01 135 | Mesh type shelf for FN 500  |
| R 01 111 | Mesh type shelf for FN 500P |
| K 23 031 | Shelf carrier for FN 300    |
| K 23 047 | Shelf carrier for FN 400    |
| K 23 048 | Shelf carrier for FN 400P   |
| K 23 046 | Shelf carrier for FN 500    |
| K 23 040 | Shelf carrier for FN 500P   |

Note: 2 pcs. shelf carrier should be ordered for each shelf



**NUVE SANAYİ MALZEMELERİ İMALAT VE TİCARET A.Ş.**

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nuve.com.tr sales@nuve.com.tr

ISO 9001: 2008

ISO 13485: 2003



## NÜVE SANAYİ MALZEMELERİ İMALAT VE TİCARET ANONİM ŞİRKETİ

Saracalar Mahallesi Saracalar Kümeevleri No:4/2 Akyurt Ankara, Türkiye

**Laboratuvar ve Sterilizasyon Cihazları Tasarımı, Üretimi,  
Satış ve Satış Sonrası Hizmetleri**

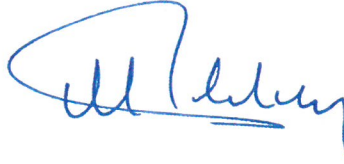
kapsamında

### ISO 9001:2015

Uluslararası kalite sistem standardına uygun  
bir kalite yönetim sistem kurmuştur.

*"Standardın aşağıda verilen maddeleri hariç tutulmuştur"*  
*"Hariç tutma yoktur"*

|                          |                 |
|--------------------------|-----------------|
| Sertifika No             | : M 8215        |
| İlk Belgelendirme Tarihi | : 28 Nisan 2010 |
| Sertifika Tarihi         | : 11 Mart 2022  |
| Son Geçerlilik Tarihi    | : 10 Mart 2025  |

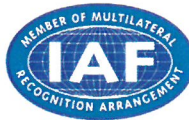


Genel Müdür

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Sertifikalar periyodik ara denetimlerin  
başarılı ile tamamlanması kaydıyla  
geçerlidir. Detaylı bilgi için yukarıdaki  
numaralara başvurulabilir.



TÜRKAK BDS NO  
YS-41C6-6EFA

## NÜVE SANAYİ MALZEMELERİ İMALAT VE TİCARET ANONİM ŞİRKETİ

Saracalar Mahallesi Saracalar Kümeevleri No:4/2 Akyurt Ankara, Turkey

**Design, Manufacture, Sales And After Sales Services Of Laboratory  
And Sterilization Equipments**

with a scope of

### ISO 9001:2015

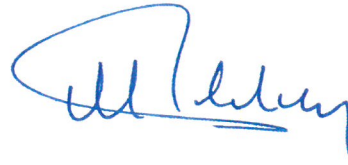
Has established a quality management system in accordance  
with international standard.

*"Following elements of the standard are excluded"*  
*"None"*

|                            |                 |
|----------------------------|-----------------|
| Certificate No             | : M 8215        |
| Initial Certification Date | : 28 April 2010 |
| Certification Date         | : 11 March 2022 |
| Expiration Date            | : 10 March 2025 |

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General Manager

Certificate is valid till expiration date,  
subject to successful completion of  
periodical surveillance audits.  
Please contact above numbers for  
detailed information.



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**Laboratuvar ve Sterilizasyon Cihazları Tasarımı, Üretimi,  
Satış ve Satış Sonrası Hizmetleri**

kapsamında

### EN ISO 13485:2016

Uluslararası Tıbbi Cihazlar Kalite Yönetim Sistemi Standardına uygun bir yönetim  
sistemi kurmuştur.

*"Standardın aşağıda verilen maddeleri hariç tutulmuştur"*

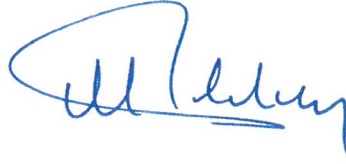
*"7.5.5" "7.5.7" "7.5.9.2"*

|                          |                 |
|--------------------------|-----------------|
| Sertifika No             | : M 8216        |
| İlk Belgelendirme Tarihi | : 28 Nisan 2010 |
| Sertifika Tarihi         | : 11 Mart 2022  |
| Son Geçerlilik Tarihi    | : 10 Mart 2025  |

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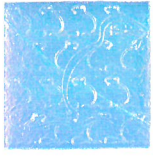
Sertifikalar periyodik ara denetimlerin  
başarılı ile tamamlanması kaydıyla  
geçerlidir. Detaylı bilgi için yukarıdaki  
numaralara başvurulabilir.



Genel Müdür



TÜRKAK BDS NO  
YS-FE6F-F002



CERTIFICATE

# NÜVE SANAYİ MALZEMELERİ İMALAT VE TİCARET ANONİM ŞİRKETİ

Saracalar Mahallesi Saracalar Kümeevleri No:4/2 Akyurt Ankara, Turkey

**Design, Manufacture, Sales And After Sales Services Of Laboratory  
And Sterilization Equipments**

with a scope of

## EN ISO 13485:2016

Has established a management system in accordance  
with international Medical Devices Quality Management System Standard

*"Following elements of the standard are excluded"*

*"7.5.5" "7.5.7" "7.5.9.2"*

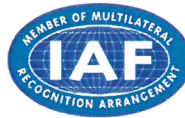
|                            |                 |
|----------------------------|-----------------|
| Certificate No             | : M 8216        |
| Initial Certification Date | : 28 April 2010 |
| Certification Date         | : 11 March 2022 |
| Expiration Date            | : 10 March 2025 |

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General Manager

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